REMARKS

Claims 45-47 and 49-89 are pending in application. Claims 56 and 58-86 are withdrawn from consideration as being drawn to a non-elected species.

Claims 45 and 88 are rejected under 35 U.S.C. §112, second paragraph as being indefinite.

Claims 45 and 88 are amended to use the term "reservoir" throughout the claims. The reservoir is the internal hollow element indicated in Figure 1 of the present application as reference numeral 1, for example. A consistent use of "reservoir" throughout the claims is believed to address the 35 U.S.C. §112, second paragraph rejection.

Claims 45, 46, 47, 49, 50, 52, 87 and 88 are rejected as anticipated by YAMASHITA JP 55-073352. This rejection is respectfully traversed.

Claim 1 of the present invention provides that the casing forms a peripheral shell surrounding an external surface of the reservoir with virtually zero clearance and claim 87 further provides that the casing directly contacts said external surface of the reservoir.

As seen in Figure 1 of YAMASHITA, there is a gap between cylinder main body 11 (reservoir) and the holder 17 (casing).

In addition, claim 45 further provides that the casing axially forces the reservoir against the base of the needle and strengthens the reservoir against pressures generated by said axial forces and generated by the ejection of the semisolid formulation.

As set forth on page 5, line 37 through page 6, line 8 of the present application, the reservoir and needle are assembled together at the needle base and held by the casing such that the casing prevents axial separation of the reservoir from the needle.

In contrast, the purpose of YAMASHITA is to allow axial expansion due to thermal expansion and contraction. Specifically, the cylinder main body 11 is able to slide with respect to the cap 13. As set forth in the constitution of YAMASHITA, the elasticity of the O ring 14 adsorbs movement of the cylinder main body 11 caused by thermal expansion and contraction due to the change of the temperature.

Further, the abstract of YAMASHITA provides that this arranges for pouring chemicals and body liquids into an object. YAMASHITA does not disclose or suggest forming a reservoir prefilled with a semi-solid preparation to be injected as further recited in claim 45. Thus, YAMASHITA could not perform the function of very high resistance against deformation due to the

pressure which would be raised during the injection of a semi-solid preparation.

Claims 46, 47, 49, 50, 52, 87 and 88 depend from claim 45 and further define the invention and are also believed patentable over YAMASHITA.

In addition, as set forth above regarding claim 87, the casing of YAMASHITA does not directly contact the external surface of the reservoir. Claim 88 provides that an entirety of the external surface of the reservoir contacts and internal surface of the casing. Such a feature is not disclosed or suggested by YAMASHITA.

Claims 45, 46, 49, 50 and 87-89 are rejected as anticipated by THRELFALL 368,627. This rejection is respectfully traversed.

As disclosed on lines 57-70 of THRELFALL, for example, liquid is drawn into the inner barrel A and then on a downward stroke forced through holes b into outer cylinder d such that the outer cylinder d is a reservoir for fluid.

Accordingly, THRELFALL does not teach or suggest that the casing forms a peripheral shell surrounding an external surface of the reservoir with virtually zero clearance as recited in claim 45 of the present application. In addition, the above passage of THRELFALL teaches that the syringe barrel A (reservoir) is drawn upward or backward by unscrewing screw-caps

e and f to release the elastic packing c from the holes b. This can be seen by comparing Figures 1 and 2 of THRELFALL wherein Figure 1 shows the needle fully extended and Figure 2 shows the needle partially withdrawn into the casing d. THRELFALL does not disclose or suggest that the casing axially forces the reservoir against the base of the needle and strengthens the reservoir against pressures generated by said axial forces and generated by the injection of the semisolid formulation.

Further, the reference to THRELFALL is directed to fluids for treating diseases, not semi-solid preparations as recited in claim 45 of the present application.

Claims 46, 49, 50 and 87-88 depend from claim 45 and further define the invention and are also believed patentable over the cited prior art.

Claim 89 of the present invention provides that an internal surface of the housing directly contacts an external surface of the reservoir along the entirety of the external surface. As set forth above regarding claim 45, THRELFALL teaches that the external casing is itself a reservoir and as such there would not be contact between an internal surface of the housing and an external surface of the reservoir along an entirety of the external surface as recited.

In addition, claim 89 provides that the needle is fixedly engaged between the reservoir and the housing. As set

forth above regarding claim 45, the needle of THRELFALL is slidably engaged between the reservoir and the housing.

As the reference does not disclose that which is recited, the anticipation rejection is not viable. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 45-47, 49, 50, 57, and 87-89 are rejected as anticipated by HIGASHIKAWA 5,704,918. This rejection is respectfully traversed.

Claim 45 provides that the base of the needle comes into contact with one end of the reservoir. Based on Applicants understanding of HIGASHIKAWA, needle 109, 209, 309, 409 indicated in Figures 6, 7 and 10-13 as noted in the Official Action appear to be compression fit onto the end of outer housing 102, 202 such that a base of the needle does not come into contact with one end of the reservoir. Claim 45 further provides that the reservoir and the needle are held fastened to each other at the base by the casing. As set forth above, the needle appears to be connected to the casing not fastened to the reservoir.

Claim 44 further provides that the casing axially forces the reservoir against the base of the needle and strengthens the reservoir against pressures generated by axial forces and generated by the injection of the semisolid

formulation. None of the embodiments of HIGASHIKAWA disclose or suggest this feature.

Claims 46, 47, 49, 50, 57 and 87-88 depend from claim 45 and further define the invention and are also believed patentable over HIGASHIKAWA.

Regarding claim 89, further clarification of what is considered the reservoir in HIGASHIKAWA is respectfully requested. Specifically, Applicants understanding of HIGASHIKAWA is that the reservoir is element 116. However, part of the element 116 extends beyond housing 102 such that the housing does not surround an entirety of the reservoir as recited in claim 89. In addition, claim 89 provides that the needle is fixedly engaged between the reservoir and the housing. HIGASHIKAWA does not disclose or suggest this feature.

Claims 45-47, 49-52 and 87-89 are rejected as anticipated by PARK 6,475,193. This rejection is respectfully traversed.

Claim 45 provides that a base of the needle comes into contact with one end of the reservoir and that the piston comes into direct contact with the base, for the purpose of injecting the dose contained in the reservoir.

Figure 2 of PARK (noted in the Official Action) shows a hollow reservoir 2, a piston 3a and a needle 4 having a base 4a. Based on Applicants understanding of PARK, the base 4a is

connected to clamp 40 which is further connected to connector 20. The base 2a of the hollow reservoir 2 is then inserted into the connector. Based on this configuration, the needle does not come into contact with one end of the reservoir. In addition, the piston is not in direct contact with the base of the needle. Further clarification of the Examiner's understanding of PARK is respectfully requested.

In addition, claim 45 provides that the reservoir and the needle are held fastened to each other at the base by the casing. It appears that the needle of PARK is held by clamp 40 which is connected to connector 20 which is then held by casing 10.

Claim 45 further provides that the casing axially forces the reservoir against the base of the needle and strengthens the reservoir against pressures generated by the axial forces and generated by the injection of semisolid formulation.

The inset of Figure 3 of PARK best shows the relationship between the reservoir 2, the casing 10 and the needle 4. As seen in Figure 3 of PARK, the connector 20 includes at least a non-return valve 32 between the reservoir 2 and the needle 4. The casing 10 surrounds the connector and reservoir. However, the casing does not axially force the reservoir against the base of the needle and does not strengthen the reservoir

against pressures generated by the axial forces and generated by the injection of semisolid formulation as recited in claim 45 of the present application.

Further, column 1, lines 6-10 of PARK disclose that the invention is related to a liquid dose, not a semi-solid formulation. As the reference does not disclose that which is recited, the anticipation rejection is not viable. Reconsideration and withdraw of the rejection are respectfully requested.

Claims 46, 47, 49-52 and 87-88 depend from claim 45 and further define the invention that are also believed patentable over PARK.

Claim 89 provides that an internal surface of the housing directly contacts an external surface of the reservoir along an entirety of the external surface. Claim 89 further provides that the needle is fixedly engaged between the reservoir and the housing. As seen in Figure 3 of PARK, less than an entirety of the external surface of the reservoir contacts the internal surface of the housing 10. As set forth above regarding claim 45, the needle 4 of PARK is external to the housing 10 and is not fixedly engaged between the reservoir and the housing as recited in claim 89.

Claims 45-47, 49-55 and 57 are rejected as being unpatentable over YAMASHITA and further in view of HIGASHIKAWA. This rejection is respectfully traversed.

As set forth above, neither YAMASHITA nor HIGASHIKAWA disclose what is recited in claim 45. Accordingly, their combination could not render obvious claim 45. Claims 46, 47, 49-55 and 57 depend from claim 45 and further define the invention and are also believed patentable over the proposed combination of references.

In the Official Action of July 23, 2002, claim 45 was indicated as generic. Since claim 45 is generic and believed allowable, claims 56 and 58-86 which depend therefrom should be examined and allowed.

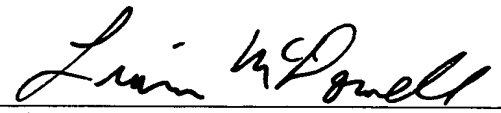
In view of the present amendment and the foregoing remarks, it is believed that the present application has been placed in condition for allowance. Reconsideration and allowance are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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